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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,086	03/26/2001	Dale Baskin	7414.0043	2844

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EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	7

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,086	BASKIN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *51-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

Election/Restriction

1. Applicant's election of Group I, claims 1-50 and 68 without traverse of in Paper No. 6 is acknowledged since there is no argument regarding the restriction requirement, it is considered to be the election without traverse.

2. Claims 51-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group II, there being no allowable generic or linking claim. Election was made **without** traverse.

Claim Rejections - 35 USC § 112

3 The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7, 10-12, 23, 25-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 10 and 35 are vague and indefinite because of the language "is derived from". By in large, the language "is derived from" is used to describe a chemical compound which has chemical modification. Thus, it is unclear whether or not the nucleic acid from the virus or prokaryote as listed in the claims is chemically modified? Clarification is required.

b. Claims 11-12 and 36-37 are vague and indefinite because of the language "...selected from..." which is improper Markush language. Clarification is required.

c. Claims 23, 25, 48 and 50 are vague and indefinite because of the language "...selected from a group comprising..." which is improper Markush language. Clarification is required.

d. Claims 7 and 31 are vague and indefinite because of the language "wherein the amplifying results in different amplification products". It has no antecedent basis.

e. Claims 26-50 are vague and indefinite because it is unclear the target nucleic acid is amplified in which reaction composition, since there are two reaction compositions in claim 26. Moreover, it is unclear how the at least one amplification product is determined for its presence in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition since the first composition does not have a fluorescent indicator as recited in claim 26. It is also unclear how the sequence of the at least one amplification product of the first reaction composition is determined since the first reaction composition does not has a fluorescence indicator. Thus, the clarification is required.

f. Claim 49 is vague and indefinite because it is unclear what is the definition of the language "a 5'-nuclease fluorescent indicator" based upon the disclosure of the specification (See pg. 9, second paragraph).

Claim Rejections - 35 USC § 103

5 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-25 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol.(4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465).

Pritham et al. disclose a rapid PCR method to monitor the amplification by detecting the fluorescent signal (See pg. 404, the abstract) involving using fluorescence probe (See pg. 405 column 2, second paragraph and pg 406 column 2 to pg. 409, column 1). The teachings of Pritham et al. are recited through out the limitations of claims 1-9, 19-24, except that Pritham et al do not disclose the sequencing method used to detect a specific target nucleic acid as recited in the limitations of claim 1. Pritham et al. also do not indicate the source of the DNA sample used in the method.

Johnston-Dow et al. disclose a method for typing HLA class I gene and the method involving DNA sequencing techniques (See the Abstract and column 9, lines 9-22). The method is to provide for the specific DNA sequencing of HLA-A, HLA-B and HLA-C (See column 3, lines 19-22). Johnston-Dow et al. also disclose that any source of human nucleic acid can be used, for example, blood and lymphoblostoid cell lines (See column 6, lines 9-14) as recited in the limitations of claims 10 and 25. Johnston-Dow et al. further indicate that HLA typing is performed routinely in connection with many medical indications, the study of auto-immune disease and the determination of susceptibility to infectious disease (See column 1, lines 57-62). This teaching suggests the limitations of claims 11-18 in that the pathogen will be from a virus, prokaryote and eukaryote, the presence of the given target polynucleotide indicates the presence of the genetic disease or a specific allele which can indicate serotype.

It would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al. and Johnston-Dow et al. to carry out

the method as claimed with a reasonable expectation of success. The motivation is that the teachings of Pritham et al. indicate that fluorescent monitoring of PCR provide qualitative and quantitative information in that the qualitative information includes purity and identity (See pg. 404, column 1, last paragraph) and rapid cycle PCR is an ideal technique for fluorescence monitoring because temperature gradients withing samples are minimized (See pg. 404, column 2, second paragraph) and the method of Johnson-Dow et al. applied the locus-specific nucleic acid amplification followed by sequence-specific detection of the amplified product for the DNA typing of HLA class I gene via DNA sequencing in that by sequencing the exons in both directions, the effect of sequencing errors on the assignment of HLA type is minimized and the method greatly reduces the number of reagents and the complexity of the sequencing protocols required (See column 9, lines 29-37).

7. Claims 26-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol.(4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465) as applied to claims 1-25 and 68 above, and further in view of Wittwer et al. (6,174,670).

The teachings of Pritham et al. and Johnston-Dow et al. are set forth in section 6 above. The teachings of Pritham et al. and Johnston-Dow et al. do not indicate that there are two reaction compositions involved in the methods.

Wittwer et al. disclose methods of monitoring hybridization during polymerase chain reaction using two pairs of oligonucleotides and a nucleic acid binding fluorescent dye to monitor amplification of a selected template (See column 13, lines 62 to column 14, lines 29).

Thus, it would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al. , Johnston-Dow et al. and Wittwer et al. to carry out the method as claimed with a reasonable expectation of success. The motivation of combining the teachings of Pritham et al. and Johnston-Dow et al. are discussed in section 6 above and the motivation of applying the teachings of Wittwer et al. is that the method of Wittwer et al. improves the sensitivity of PCR quantification and reduces the time of fluorescence monitoring for PCR.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 27, 2002

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600